#6152 P.009 OGT.09'2002 15:16

U.S.S.N. 09/658,390

Filed: September 8, 2000

AMENDMENT AND RESPONSE TO OFFICE ACTION

Rejection Under 35 U.S.C. § 102

Claims 38-49 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent

No. 5,700.873 to Zajaczkowski et al. ("Zajaczkowski"). Applicants respectfully traverse this

rejection to the extent that it is applied to the claims as amended.

Zajaczkowski discloses a water-soluble or water-dispersible copolymer. Zajaczkowski

teaches that the copolymer does not form a gel (see abstract and col. 3, lines 4-8). In contrast,

the claimed compositions must be capable of forming a gel upon polymerization. Thus, the

claims as amended are novel in view of Zajaczkowski.

Rejection Under 35 U.S.C. § 103

Claims 38-49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over

Zajaczkowski. Applicants respectfully traverse this rejection to the extent that it is applied to the

claims as amended.

As discussed above, Zajaczkowski teaches the formation of a water-soluble material that

does not gel upon polymerization. Zajaczkowski teaches that the formation of gels is

problematic since gels cannot be processed for their desired applications (col. 1, lines 19-26).

Thus, Zajaczkowski teaches away from the claimed compositions, which are capable of forming

gels upon polymerization. Therefore, the claims, as amended are not obvious over

Zajaczkowski.

ATL1 #543173v1

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FTT 126 077637/00017

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AMENDMENT AND RESPONSE TO OFFICE ACTION

Allowance of claims 38-49, as amended, is respectfully solicited.

Respectfully submitted,

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Date: October 9, 2002

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Certificate of Facsimile Transmission

I hereby certify that this Amendment and Response to Office Action, and any documents referred to as attached therein are being facsimile transmitted on this date, October 9, 2002 to the Commissioner for Patents, U.S. Patent and Trademark Office, Washington, DC 20231.

<u>Dam Jarabough</u> Pam Turnbough

Date: October 9, 2002

ATLI #543173vE

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MARKED UP VERSION OF AMENDMENTS PURSUANT TO 37 C.F.R. § 1.121

Marked Up Version of Amended Claims Pursuant to 37 C.F.R. § 1.121(c)(1)(ii)

Please cancel claims 1-37.

(Amended) A composition for forming a water-absorbing, high modulus 38. polymeric material comprising at least one macromer and at least one monomer,

wherein the macromer comprises hydrophobic and hydrophilic regions and has a molecular weight of 500 to 200,000 Da,

wherein the monomer contains at least one vinyl group and has a molecular weight of less than 1,000 Da, and

wherein the monomer comprises at least 30% (wt/wt) of the composition, and wherein the composition is capable of forming a gel upon polymerization.

- The composition of claim 38, wherein the composition is in the form of a fluid or 39. paste.
 - The composition of claim 38, further comprising water. 40.
- The composition of claim 38, wherein the macromer is polyethyleneglycol-41. trimethylene carbonate-diacrylate.
- The composition of claim 38, wherein the monomer is selected from the group 42. consisting of vinyl caprolactam, methyl acrylate, methyl methacrylate, styrene, N-vinyl pyrrolidone, and N-vinyl imidazole, diacetone acrylamide, vinyloxyethanol, 2-acrylamido-2methylpropane, and methyl acryloyl lactate and mixtures and derivatives thereof.

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MARKED UP VERSION OF AMENDMENTS PURSUANT TO 37 C.F.R. § 1.121

The composition of claim 38, wherein the macromer comprises up to 50% (wt/wt) 43. of the formulation and the monomer comprises at least 45% (wt/wt) of the formulation.

- The composition of claim 43, further comprising less than 40% (wt/wt) water. 44.
- The composition of claim 41, wherein the monomer is diacetone acrylamide. 45.
- The composition of claim 38, 46.

wherein upon copolymerization of the macromer and monomer, a polymeric material is formed, wherein the material comprises hydrophobic and hydrophilic regions and is characterized as having the following properties:

- absorbing water to less than about 300% of its initial weight, on equilibration with a) water or bodily liquids;
- having a solids content of at least about 20% after equilibration in water or bodily b) Jiquids;
 - having an elongation to failure of at least about 25% hydration to equilibrium; and c)
- being sufficiently biocompatible to permit the treatment or repair of biological d) tissue, or used as an implant in a patient.
- The composition of claim 38, wherein the macromer has the formula AHK, 47. wherein:

A is a residue of an ethylenically unsaturated acid that is linked to H by a bond selected from ester and amide;

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MARKED UP VERSION OF AMENDMENTS PURSUANT TO 37 C.F.R. § 1.121

H is the residue of a hydroxy carboxylic acid, a carbonic acid, or an amino acid, which is linked to K by an ester bond; and

K is the residue of an alcohol containing at least one carbon atom.

The composition of claim 47 wherein 48.

A is selected from the group consisting of acrylic, methacrylic crotonic, isocrotonic, tiglic, angelic, and cinnamic acids; maleic, fumaric, citraconic, mesaconic, itaconic, citric and isocitric acids, and monoesters and monoamides thereof, and mixtures thereof;

H is selected from the group consisting of glycolic acid, lactic acid, 3-hydroxy-propanoic acid, a hydroxybutyric acid, a hydroxypentanoic acid, hydroxy trimethylene carbonic acid, hydroxy ethylene carbonic acid, hydroxy propylene carbonic acid, hydrolyzed dioxanone, a hydroxyhexanoic acid, an alpha, beta or gamma amino acid of eight carbons or fewer, and mixtures thereof; and

K is an alcohol containing from 1 to about 10 carbon atoms and at least one hydroxyl group, or a mixture of such alcohols.

The composition of claim 48 wherein A is selected from the group consisting of 49. acrylic acid and methacrylic acid.